

# UNDERSTANDING THE FUNCTIONAL LIMITS OF SINGLE USE COMPONENTS THROUGH PRESSURE TESTING

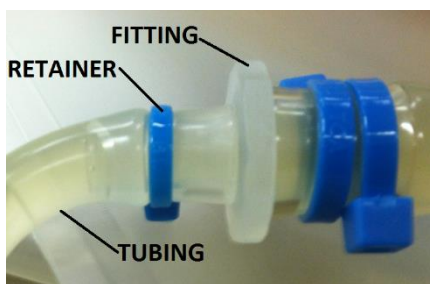
Jon Schultz, Design Engineer, Thermo Fisher Scientific  
jonathan.schultz@thermofisher.com

## Summary:

Transferring fluid from one container to another is a very common bioprocessing operation. A variety of different components have been created for the purpose of fluid transfer, including bag ports, tubing, aseptic connectors, barbed fittings, tubing retainers, etc. In order to provide high quality, highly reliable single use assemblies, it is important to test the functional limits of fluid transfer components. Thermo Fisher has designed a versatile system to test the pressure limits of components.

## Tubing Connections:

Tubing, fitting, retainer. What are its functional limits?



## Connection Test Unit:

- Pressure decay technology – quantifiable leak rate, long pressure hold durations, inexpensive operation
- Test temperature is controllable
- Tubing manipulation is controllable
- 80 psi maximum test pressure
- Complete range of fitting/tubing sizes

## Case Studies:

Each of the case studies below have been investigated, with interesting and enlightening results.

1. If a tubing is bent or kinked, does it affect the leak resistance of the connection?
2. What is the optimal Barb Design?
3. Does location of cable tie or other retainer effect leak resistance?
4. How do different tubing materials compare to one another? (Silicone, PVC, TPE)
5. Can we make product improvement recommendations based on pressure testing?

## Conclusion:

Testing of single use components exposes the functional limits of those components. Such testing is the foundation of fit-for-purpose single use design.

Thermo Fisher is currently working to better understand all components that are used on our products. A wide variety of test scenarios are being considered and tested.